CABINET FOR HEALTH AND FAMILY SERVICES

Department for Medicaid Services

Commissioner's Office

(Amendment)

907 KAR 1:019. Outpatient Pharmacy Program**.**

RELATES TO: KRS Chapter 13B, 205.510, 205.560, 205.561, 205.5631-205.5639, 205.564, 205.6316, 205.8451, 205.8453, 217.015, 217.822, 42 C.F.R. 430.10, 431.54, 440.120, 447.331, 447.332, 447.333, 447.334, 42 U.S.C. 1396a, 1396b, 1396c, 1396d, 1396r-8

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.561, 205.5632, 205.5634, 205.5639(2), 205.564(10), (13)[~~, 2010 Extra. Sess. Ky. Acts ch. 1, Part I.G.3.b.(26)~~]

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has the responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law for the provision of medical assistance to Kentucky's indigent citizenry. KRS 205.560 provides that the scope of medical care for which Medicaid shall pay is determined by administrative regulations promulgated by the cabinet. This administrative regulation establishes the provisions for coverage of drugs through the Medicaid Outpatient Pharmacy Program.

Section 1. Definitions. (1) "Brand name drug" means the registered trade name of a drug which was originally marketed under an original new drug application approved by the Food and Drug Administration.

(2) "Commissioner" is defined by KRS 205.5631(1).

(3) "Covered drug" means a drug for which the Department for Medicaid Services provides reimbursement if medically necessary and if provided, but not otherwise excluded, in accordance with Sections 2 and 3 of this administrative regulation.

(4) "Covered outpatient drug" is defined by 42 U.S.C. 1396r-8(k)(2).

(5) "Department" means the Department for Medicaid Services or its designated agent.

(6) "Department's pharmacy Internet Web site" or "Web site" means the Internet Web site maintained by the Department for Medicaid Services and accessible at http://www.chfs.ky.gov/dms/Pharmacy.htm.

(7) "Dosage form" means the type of physical formulation used to deliver a drug to the intended site of action, including a tablet, an extended release tablet, a capsule, an elixir, a solution, a powder, a spray, a cream, an ointment, or any other distinct physical formulation recognized as a dosage form by the Food and Drug Administration.

(8) "Drug list" means the Department for Medicaid Services' list which:

(a) Specifies:

1. Drugs, drug categories, and related items not covered by the department; and

2. Covered drugs requiring prior authorization or having special prescribing or dispensing restrictions or excluded medical uses; and

(b) May include information about other drugs, drug categories, or related items and

dispensing and prescribing information.

(9) "Drug Management Review Advisory Board" or "DMRAB" or "board" means the board established pursuant to KRS 205.5636.

(10) "Effective" or "effectiveness" means a finding that a pharmaceutical agent does or does not have a significant, clinically-meaningful therapeutic advantage in terms of safety, usefulness, or clinical outcome over the other pharmaceutical agents based on pertinent information from a variety of sources determined by the department to be relevant and reliable.

(11) "Emergency supply" means a seventy-two (72) hour supply.

(12) “Enrollee” means a recipient who is enrolled with a managed care organization.

(13) "Federal financial participation" is defined by 42 C.F.R. 400.203.

(14)[~~(13)~~] "Food and Drug Administration" means the Food and Drug Administration of the United States Department of Health and Human Services.

(15)[~~(14)~~] "Generic drug" or "generic form of a brand name drug" means a drug which contains identical amounts of the same active drug ingredients in the same dosage form and which meets official compendia or other applicable standards of strength, quality, purity, and identity in comparison with the brand name drug.

(16)[~~(15)~~] "Legend drug" means a drug so defined by the Food and Drug Administration and required to bear the statement: "Caution: Federal law prohibits dispensing without prescription".

(17) “Managed care organization” means an entity for which the Department of Medicaid Services has contracted to serve as a managed care organization as defined in 42 C.F.R. 438.2.

(18)[~~(16)~~] "Manufacturer" is defined in 42 U.S.C. 1396r-8(k)(5).

(19)[~~(17)~~] "Medically necessary" or "medical necessity" means that a covered benefit is determined to be needed in accordance with 907 KAR 3:130.

(20)[~~(18)~~] "Official compendia" or "compendia" is defined in 42 U.S.C. 1396r-8(g)(1)(B)(i).

(21)[~~(19)~~] "Over-the-counter drug" or "OTC drug" means a drug approved by the Food and Drug Administration to be sold without bearing the statement "Caution: Federal law prohibits dispensing without prescription".

(22)[~~(20)~~] "Pharmacy and Therapeutics Advisory Committee" or "committee" or "P&T Committee" means the pharmacy advisory committee established by KRS 205.564.

(23)[~~(21)~~] "Prescriber" means a health care professional who:

(a) within the scope of practice under Kentucky licensing laws, has the legal authority to write or order a prescription for the drug that is ordered;

(b) Is enrolled in the Medicaid Program pursuant to 907 KAR 1:672; and

(c) Is currently participating in the Medicaid Program pursuant to 907 KAR 1:671.

(24)[~~(22)~~] "Recipient" is defined by KRS 205.8451(9).

(25)[~~(23)~~] "Secretary" means the Secretary of the Cabinet for Health and Family Services.

(26)[~~(24)~~] "Supplemental rebate" means a cash rebate that offsets a Kentucky Medicaid expenditure and that supplements the Centers for Medicare and Medicaid Services National Rebate Program.

Section 2. Covered Benefits and Drug List. (1) A covered outpatient drug, nonoutpatient drug, or diabetic supply covered via this administrative regulation shall be:

(a) Medically necessary;

(b) Approved by the Food and Drug Administration; and

(c) Prescribed for an indication that has been approved by the Food and Drug Administration or for which there is documentation in official compendia or peer-reviewed medical literature supporting its medical use.

(2) A covered outpatient drug covered via this administrative regulation shall be prescribed on a tamper-resistant pad unless exempt pursuant to subsection (3) of this section.

(3) The tamper-resistant pad requirement established in subsection (2) of this section shall not apply to:

(a) An electronic prescription;

(b) A faxed prescription; or

(c) A prescription telephoned by a prescriber.

(4) To qualify as a tamper-resistant pad prescription, a prescription shall contain:

(a) One (1) or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

(b) One (1) or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; and

(c) One (1) or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

(5) (a) Except as provided in paragraph (b) of this subsection, the department shall cover the diabetic supplies listed in this paragraph via the department’s pharmacy program and not via the department’s durable medical equipment program established in

907 KAR 1:479:

1. A syringe with needle (sterile, 1cc or less);

2. Urine test or reagent strips or tablets;

3. Blood ketone test or reagent strip;

4. Blood glucose test or reagent strips for a home blood glucose monitor;

5. Normal, low, or high calibrator solution, chips;

6. Spring-powered device for lancet;

7. Lancets per box of 100; or

8. Home blood glucose monitor.

(b) The department shall cover the diabetic supplies listed in this paragraph via the department's durable medical equipment program established in 907 KAR 1:479 if:

1. The supply has an HCPCS code of A4210, A4250, A4252, A4253, A4256, A4258, A4259, E0607 or E2100;

2. The supply has an a HCPCS code of A4206 and a diagnosis of diabetes is present on the corresponding claim; or

3. Medicare is the primary payor for the supply.

(6) The department shall have a drug list which:

(a) Lists:

1. Drugs, drug categories, and related items not covered by the department and, if applicable, excluded medical uses for covered drugs; and

2. Maintenance drugs covered by the department;

(b) Specifies those covered drugs requiring prior authorization or having special prescribing or dispensing restrictions;

(c) Specifies those covered drugs for which the maximum quantity limit on dispensing may be exceeded;

(d) Lists covered over-the-counter drugs;

(e) Specifies those legend drugs which are permissible restrictions under 42 U.S.C. 1396r-8(d), but for which the department makes reimbursement;

(f) May include a preferred drug list of selected drugs which have a more favorable cost to the department and which prescribers are encouraged to prescribe, if medically appropriate;

(g) May be updated monthly or more frequently by the department; and

(h) Shall be posted on the department's Internet pharmacy Web site.

(6)(a) The department may implement drug treatment protocols requiring the use of medically-appropriate drugs which are available without prior authorization before the use of drugs which require prior authorization.

(b) The department may approve a request from the prescriber or a pharmacist for exemption of a specific recipient from the requirement established in paragraph (a) of this subsection, based on documentation that drugs available without prior authorization:

(a) Were used and were not an effective medical treatment or lost their effectiveness;

(b) Are reasonably expected to not be an effective medical treatment;

(c) Resulted in, or are reasonably expected to result in, a clinically-significant adverse reaction or drug interaction; or

(d) Are medically contraindicated.

Section 3. Exclusions and Limitations. (1) The following drugs shall be excluded from

coverage:

(a) A drug which the Food and Drug Administration considers to be:

1. A less-than-effective drug; or

2. Identical, related, or similar to a less-than-effective drug;

(b) A drug or its medical use in one (1) of the following categories unless the drug or its medical use is designated as covered in the drug list:

1. A drug if used for anorexia, weight loss, or weight gain;

2. A drug if used to promote fertility;

3. A drug if used for cosmetic purposes or hair growth;

4. A drug if used for the symptomatic relief of cough and colds;

5. Vitamin or mineral products other than prenatal vitamins and fluoride preparations;

6. An over-the-counter drug provided to a Medicaid nursing facility service recipient if included in the nursing facility's standard price;

7. A barbiturate;

8. A benzodiazepine;

9. A drug which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; or

10. A drug utilized for erectile dysfunction therapy unless the drug is used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the United States Food and Drug Administration;

(c) A drug for which the manufacturer has not entered into or complied with a rebate agreement in accordance with 42 U.S.C. 1396r-8(a), unless there has been a review

and determination by the department that it is in the best interest of a recipient for the department to make payment for the drug and federal financial participation is available for the drug;

(d) A drug dispensed as part of, or incident to and in the same setting as, an inpatient hospital service, an outpatient hospital service, or an ambulatory surgical center service;

(e) A drug for which the department requires prior authorization if prior authorization has not been approved; and

(f) A drug that has reached the manufacturer's termination date, indicating that the drug may no longer be dispensed by a pharmacy.

(2) If authorized by the prescriber, a prescription for a:

(a) Controlled substance in Schedule III-V may be refilled up to five (5) times within a six (6) month period from the date the prescription was written or ordered, at which time a new prescription shall be required; or

(b) Noncontrolled substance, except as prohibited in subsection (4) of this section, may be refilled up to eleven (11) times within a twelve (12) month period from the date the prescription was written or ordered, at which time a new prescription shall be required.

(3) For each initial filling or refill of a prescription, a pharmacist shall dispense the drug in the quantity prescribed not to exceed a thirty-two (32) day supply unless:

(a) The drug is designated in the department's drug list as a drug exempt from the thirty-two (32) day dispensing limit in which case the pharmacist may dispense the quantity prescribed not to exceed a three (3) month supply or 100 units, whichever is greater;

(b) A prior authorization request has been submitted on the Drug Prior Authorization Request Form (MAP-82001) and approved by the department because the recipient needs additional medication while traveling or for a valid medical reason, in which case the pharmacist may dispense the quantity prescribed not to exceed a three (3) month supply or 100 units, whichever is greater;

(c) The drug is prepackaged by the manufacturer and is intended to be dispensed as an intact unit and it is impractical for the pharmacist to dispense only a month's supply because one (1) or more units of the prepackaged drug will provide more than a thirty-two (32) day supply; or

(d) The prescription fill is for an outpatient service recipient, excluding an individual who is receiving supports for community living services in accordance with 907 KAR 1:145.

(4) A prescription fill for a maintenance drug for an outpatient service recipient who has demonstrated stability on the given maintenance drug, excluding an individual receiving supports for community living services in accordance with 907 KAR 1:145 or 907 KAR 12:010, shall be dispensed in a ninety-two (92) day supply unless:

(a) The department determines that it is in the best interest of the recipient to dispense a smaller supply; or

(b) The recipient is covered under the Medicare Part D benefit in which case the department shall not cover the prescription fill.

(5) The department may require prior authorization for a compounded drug that requires preparation by mixing two (2) or more individual drugs; however, the department may exempt a compounded drug or compounded drug category from prior authorization

if there has been a review and determination by the department that it is in the best interest of a recipient for the department to make payment for the compounded drug or compounded drug category.

(6) A prescriber shall make his or her national provider identifier (NPI) available to a pharmacist, and the prescriber's NPI shall be recorded on each pharmacy claim.

(7)[~~(7)(a) Except as provided in paragraph (b), (c), or (d) of this subsection, the department shall cover no more than a total of four (4) prescriptions, of which no more than three (3) shall be brand name prescriptions per recipient per month.~~

~~(b) The four (4) prescription limit shall not apply if the recipient:~~

~~1. Is under nineteen (19) years of age;~~

~~2. Uses insulin for the management of diabetes; or~~

~~3. Is a nursing facility resident who does not have Medicare Part D drug coverage.~~

~~(c) A pharmacist may utilize a four (4) prescription limit override code for a recipient whose prescription will exceed the four (4) prescription limit if the prescription is prescribed:~~

~~1. For any of the following conditions:~~

~~a. Acute infection or infestation;~~

~~b. Bipolar disorder;~~

~~c. Cancer;~~

~~d. Cardiac rhythm disorder;~~

~~e. Chronic pain;~~

~~f. Coronary artery or cerebrovascular disease (advanced arthrosclerotic disease);~~

~~g. Cystic fibrosis;~~

~~h. Dementia;~~

~~i. Diabetes;~~

~~j. End stage lung disease;~~

~~k. End stage renal disease;~~

~~l. Epilepsy;~~

~~m. Hemophilia;~~

~~n. HIV or AIDS or immunocompromised;~~

~~o. Hyperlipidemia;~~

~~p. Hypertension;~~

~~q. Major depression;~~

~~r. Metabolic syndrome;~~

~~s. Organ transplant; or~~

~~t. Psychotic disorder; or~~

~~2. As part of:~~

~~a. Acute therapy for migraine headache or acute pain; or~~

~~b. Suppressive therapy for thyroid cancer.~~

~~(d) An additional prescription or prescriptions shall be covered if the department determines that it is in the best interest of the recipient to cover an additional prescription or prescriptions whether brand name or generic.~~

~~(8) The department shall cover up to three (3) brand name prescriptions per member per month unless the department determines that it is in the best interest of the member to cover any additional brand name prescriptions.~~

~~(9)~~] A refill of a prescription shall not be covered unless at least ninety (90) percent of

the prescription, except for a refill for a recipient who is a resident of a personal care home or a resident of a facility reimbursed pursuant to 907 KAR 1:025 or 1:065, time period has elapsed.

(b) A refill of a prescription for a recipient who is a resident of a facility or entity referenced in paragraph (a) of this subsection shall not be covered unless at least eighty (80) percent of the prescription time has lapsed.

Section 4. Prior Authorization Process. (1)(a) To request prior authorization for a drug:

1. The applicable form as required by this section shall be completed and submitted to the department:

a. By fax, mail, express delivery service, or messenger service; or

b. Via the department's pharmacy Internet Web site; or

2. A requester may provide the information required on the applicable form to the department verbally via the telephone number published on the department's pharmacy Internet Web site.

(b) If drug therapy needs to be started on an urgent basis to avoid jeopardizing the health of a recipient or to avoid causing substantial pain and suffering, the completed request form may be sent to the department’s urgent fax number or submitted to the department via the department's pharmacy Internet Web site.

(2) A Drug Prior Authorization Request Form shall be used by a:

(a) Prescriber or pharmacist to request prior authorization for a drug except for a brand name drug, Suboxone®, Subutex®, Zyvox®, Synagis®, or an atypical antipsychotic agent;

(b) Pharmacist to request an early refill of a prescription; or

(c) Pharmacist to obtain prior authorization for special dispensing requests involving exceptions to the thirty-two (32) day maximum quantity limit including additional drugs needed for travel or other valid medical reasons.

(3)(a) Except as established in paragraph (c) of this subsection, a Brand Name Drug Request Form shall be used by a prescriber to request prior authorization for a brand name drug if a generic form of the drug is available.

(b) Regarding a Brand Name Drug Request Form, a prescriber shall:

1. Complete the form;

2. Include on the form:

a. The handwritten phrase "band medically necessary" or "brand necessary"; and

b. The provider's signature for each specific drug requested; and

3. Indicate:

a. Whether the recipient has received treatment with available generic forms of the brand name drug and the length of therapy; and

b. Why the recipient's medical condition is unable to be adequately treated with the generic forms of the drug.

(c) Submission of a Brand Name Drug Request Form shall not be required if:

1. The department has specifically exempted the drug, via the drug list, from this requirement;

2. It has been determined by the department to be in the best interest of a recipient not to require submission of a Brand Name Drug Request Form; or

3. The prescriber certifies that the brand name drug is medically necessary in ac-

cordance with subsection (3)(b) of this section.

(d) In addition to the requirements established in paragraphs (a) through (c) of this subsection, the prescriber shall certify a brand name only request by including for each brand name drug requested, the prescriber's signature and the phrase "Brand Medically Necessary" or "Brand Necessary" handwritten directly on:

1. The prescription;

2. The nursing facility order sheet; or

3. A separate sheet of paper that:

a. Includes the name of the recipient and the brand name drug requested; and

b. Is attached to the original prescription or nursing facility order sheet.

(4) A Mental Health Drug Authorization Request Form for Atypical Antipsychotic Agents shall be:

(a) Used to request prior authorization for an atypical antipsychotic drug; and

(b) Completed and submitted as directed on the form.

(5) A Suboxone® and Subutex® Prior Authorization Request Form shall be:

(a) Used to request prior authorization for Suboxone® or Subutex®; and

(b) Completed and submitted as directed on the form.

(6) A Zyvox® (linezolid) Drug Authorization Request Form shall be:

(a) Used to request prior authorization for Zyvox®; and

(b) Completed and submitted as directed on the form.

(7) A Synagis® Prior Authorization Request Form shall be:

(a) Used to request prior authorization for Synagis®; and

(b) Completed and submitted as directed on the form.

(8) If a recipient presents a prescription to a pharmacist for a drug which requires prior authorization, the pharmacist:

(a) Shall, unless the form is one (1) which has to be completed by the prescriber, submit a request for prior authorization in accordance with this section;

(b) Shall notify the prescriber or the prescriber's authorized representative that the drug requires prior authorization and:

1. If the prescriber indicates that a drug list alternative available without prior authorization is acceptable and provides a new prescription, shall dispense the drug list alternative; or

2. If the prescriber indicates that drug list alternatives available without prior authorization have been tried and failed or are clinically inappropriate or if the prescriber is unwilling to consider drug list alternatives, shall:

a. Request that the prescriber obtain prior authorization from the department; or

b. Unless the form is one (1) which has to be completed by the prescriber, submit a prior authorization request in accordance with this section; or

(c) Except as restricted by subparagraphs 3 and 4 of this paragraph, may provide the recipient with an emergency supply of the prescribed drug in an emergency situation in accordance with this subsection.

1. The emergency situation shall:

a. Occur outside normal business hours of the department's drug prior authorization office, except for medications dispensed to a long term care recipient in which an emergency supply may be dispensed after 5 p.m. EST; and

b. Exist if, based on the clinical judgment of the dispensing pharmacist, it would rea-

sonably be expected that, by a delay in providing the drug to the recipient, the health of the recipient would be placed in serious jeopardy or the recipient would experience substantial pain and suffering.

2. At the time of the dispensing of the emergency supply, the pharmacist shall in accordance with this section:

a. Submit a prior authorization request to the department’s urgent fax number or to the department via the department's pharmacy Internet Web site; or

b. If applicable, notify the prescriber as soon as possible that an emergency supply was dispensed and that the prescriber is required to obtain prior authorization for the requested drug from the department.

3. An emergency supply shall not be provided for an over-the-counter (OTC) drug.

4. An emergency supply shall not be provided for a drug excluded from coverage in accordance with Section 3(1) (a), (b) or (c) of this administrative regulation.

5. The quantity of the emergency supply shall be:

a. The lesser of a seventy-two (72) hour supply of the drug or the amount prescribed; or

b. The amount prescribed if it is not feasible for the pharmacist to dispense just a seventy-two (72) hour supply because the drug is packaged in such a way that it is not intended to be further divided at the time of dispensing but rather dispensed as originally packaged.

(9)(a) If a prescriber submits a prescription to a pharmacy via telephone, the prescriber shall also fax the prescription for a controlled substance to the pharmacy within forty-eight (48) hours of submitting it via telephone.

(b) A pharmacy shall not be denied payment for services for the failure of the prescriber to fax the prescription for a controlled substance to the pharmacy if the pharmacy:

1. Requests a faxed prescription from the prescriber;

2. Documents the request for a faxed prescription; and

3. Documents that a faxed prescription, which was not received, was not received.

(10) The department's notification of a decision on a request for prior authorization shall be made in accordance with the following:

(a) If the department approves a prior authorization request, notification of the approval shall be provided by telephone, fax or via the department's pharmacy Internet Web site to the party requesting the prior authorization and, if known, to the pharmacist.

(b) If the department denies a prior authorization request:

1. The department shall provide a denial notice:

a. By mail to the recipient and in accordance with 907 KAR 1:563; and

b. By fax, telephone, or if necessary by mail to the party who requested the prior authorization.

(11)(a) The department may grant approval of a prior authorization request for a drug for a specific recipient for a period of time not to exceed 365 days.

(b) Approval of a new prior authorization request shall be required for continuation of therapy subsequent to the expiration of a time-limited prior authorization request.

(12) Prior authorization of drugs for a Medicaid long-term care recipient in a nursing facility shall be in accordance with this subsection.

(a) The department may specify in its drug list specific drugs or drug classes which

shall:

1. Not be exempted from prior authorization; or

2. Be exempt from prior authorization for Medicaid recipients in nursing facilities.

(b) A brand name drug for which the department requires completion by the prescriber of a Brand Name Drug Request Form in accordance with this section shall not be exempted from prior authorization.

Section 5. Placement of Drugs on Prior Authorization. (1) Except as excluded by Section 3(1)(a) to (c) of this administrative regulation, upon initial coverage by the Kentucky Medicaid program, a drug that is newly approved for marketing by the Food and Drug Administration under a product licensing application, new drug application, or a supplement to a new drug application and that is a new chemical or molecular entity shall be subject to prior authorization in accordance with KRS 205.5632.

(2) Upon request by the department, a drug manufacturer shall provide the department with the drug package insert information.

(3) The drug review process to determine if a drug shall require prior authorization shall be in accordance with this subsection and KRS 205.5632.

(a) The determination as to whether a drug is in an excludable category specified in Section 3(1) of this administrative regulation shall be made by the department.

1. If a drug, which has been determined to require prior authorization becomes available on the market in a new strength, package size, or other form that does not meet the definition of a new drug the new strength, package size, or other form shall require prior authorization.

2. A brand name drug for which there is a generic form that contains identical

amounts of the same active drug ingredients in the same dosage form and that meets compendial or other applicable standards of strength, quality, purity, and identity in comparison with the brand name drug shall require prior authorization in accordance with Section 4 of this administrative regulation, unless there has been a review and determination by the department that it is in the best interest of a recipient for the department to cover the drug without prior authorization.

(b) The committee shall make a recommendation to the department regarding prior authorization of a drug based on:

1. A review of clinically-significant adverse side effects, drug interactions and contraindications and an assessment of the likelihood of significant abuse of the drug; and

2. An assessment of the cost of the drug compared to other drugs used for the same therapeutic indication and whether the drug offers a substantial clinically-meaningful advantage in terms of safety, effectiveness, or clinical outcome over other available drugs used for the same therapeutic indication. Cost shall be based on the net cost of the drug after federal rebate and supplemental rebates have been subtracted from the cost.

(c)1. Within thirty (30) days of the date the committee’s recommendation is posted on the department’s pharmacy Internet Web site, the secretary, in consultation with the commissioner and the department's pharmacy staff, shall review the recommendations of the committee and make the final determination whether a drug requires prior authorization.

2. If the recommendation of the committee is not accepted, the secretary shall inform the committee of the basis for the final determination in accordance with Section 8(3) of this administrative regulation.

(4) The department may exclude from coverage or require prior authorization for a drug which is a permissible restriction in accordance with 42 U.S.C. 1396r-8(d).

Section 6. Drug Management Review Advisory Board Meeting Procedures and Appeals. (1) A person may address the DMRAB if:

(a) The presentation is directly related to an agenda item; and

(b) The person gives notice to the department (and gives a copy to the DMRAB chairperson) by fax or email at least five (5) business days prior to the meeting.

(2) A verbal presentation:

(a) In aggregate per drug per drug manufacturer shall not exceed three (3) minutes with two (2) additional minutes allowed for questions from the DMRAB, if required; or

(b) By an individual on a subject shall not exceed three (3) minutes with two (2) additional minutes allowed for questions from the DMRAB, if required.

(3) The proposed agenda shall be posted on the department's pharmacy Internet Web site at least fourteen (14) days prior to the meeting.

(4) An appeal of a final decision by the commissioner by a manufacturer of a product shall be in accordance with KRS 205.5639(5). The appeal request shall:

(a) Be in writing;

(b) State the specific reasons the manufacturer believes the final decision to be incorrect;

(c) Provide any supporting documentation; and

(d) Be received by the department within thirty (30) days of the manufacturer's actual notice of the final decision.

Section 7. Pharmacy and Therapeutics Advisory Committee Meeting Procedures. (1)

A P&T Committee meeting agenda shall be posted as required by KRS 205.564(6).

(2) A P&T committee meeting shall be conducted in accordance with KRS 205.564.

(3) A public presentation at a P&T Committee meeting shall comply with this subsection.

(a)1. A verbal presentation in aggregate per drug per drug manufacturer shall not exceed three (3) minutes with two (2) additional minutes allowed for questions from the P&T Committee, if required.

2. A verbal presentation by an individual on a subject shall not exceed five (5) minutes.

3. A request to make a verbal presentation shall be submitted in writing via fax or e-mail to the department with a copy to the chair of the P&T Committee no later than five (5) business days in advance of the P&T Committee meeting.

4. An individual may only present new information (package insert changes, new indication or peer-reviewed journal articles) on a product or information on a new product.

5. A presentation shall be limited to an agenda item.

(b) Nonverbal comments, documents, or electronic media material (limited to package insert changes, new indication, or peer reviewed journal articles) shall be:

1.a. E-mailed to the department in a Microsoft compatible format (for example, Word, Power Point, Excel or other standard file formats including Adobe Acrobat's pdf format); or

b. Mailed to the department with a total of twenty-five (25) copies mailed so that the department may distribute copies to P&T Committee members as well as to any other involved parties; and

2. Received by the department no later than seven (7) days prior to the P&T Committee meeting.

(4) The department may prepare written recommendations or options for drug review for the committee and shall post them as required by KRS 205.564(6).

(5) A recommendation by the committee shall require a majority vote.

(6) Recommendations of the committee shall be posted as required by KRS 205.564(8).

(7) A drug manufacturer may request that its name be placed on the department's distribution list for agendas of committee meetings. Placement of a drug manufacturer's name on the distribution list shall be valid through December 31 of each year, at which time the drug manufacturer shall be required to again request placement on the distribution list. To request placement of the drug manufacturer's name on the distribution list, the drug manufacturer shall submit the request in writing to the department and shall provide the following information about the drug manufacturer:

(a) Manufacturer's name;

(b) Mailing address;

(c) Telephone number;

(d) Fax number;

(e) E-mail address; and

(f) Name of a contact person.

Section 8. Review and Final Determination by the Secretary. (1) An interested party who is adversely affected by a recommendation of the committee may submit a written exception to the secretary in accordance with the following:

(a) The written exception shall be received by the secretary within seven (7) calendar days of the date of the committee meeting at which the recommendation was made; and

(b) Only information that was not available to be presented at the time of the committee's meeting shall be included in the written exception.

(2) After the time for filing written exceptions has expired, the secretary shall consider the recommendation of the committee and all exceptions that were filed in a timely manner prior to making a final determination. The secretary shall issue a final determination, and a dated public notice of the final determination shall be posted on the department's pharmacy Internet Web site for six (6) months. A copy of the final determination may be requested from the department after it is issued.

(3) The secretary shall make a final determination in accordance with KRS 205.564(9).

(4) A final determination by the secretary may be appealed in accordance with KRS Chapter 13B. A decision of the secretary to remand the recommendation to the committee shall not constitute a final decision for purposes of an appeal pursuant to KRS Chapter 13B. An appeal request shall:

(a) Be in writing;

(b) Be sent by mail, messenger, carrier service, or express-delivery service to the secretary in a manner that safeguards the information;

(c) State the specific reasons the final determination of the secretary is alleged to be erroneous or not based on the facts and law available to the committee and the secretary at the time of the decision;

(d) Be received by the secretary within thirty (30) days of the date of the posting of the final determination on the department's pharmacy Internet Web site; and

(e) Be forwarded by the secretary to the Administrative Hearings Branch of the Cabinet for Health and Family Services for processing in accordance with the provisions of KRS Chapter 13B.

Section 9. Confirming Receipt of Prescription. (1) A recipient, or a designee of the recipient, shall sign their name in a format which allows their signature to be reproduced or preserved at a pharmacy confirming that the recipient received the prescription.

(2) A pharmacist shall maintain, or be able to produce a copy of, a log of recipient signatures referenced in subsection (1) of this section for at least six (6) years.

Section 10. Exemptions to Prescriber Requirements. The department shall reimburse for:

(1) A full prescription prescribed by a provider who is not enrolled in the Kentucky Medicaid Program, if the department determines that reimbursing for a full prescription is in the best interest of the recipient; or

(2) An emergency supply of a prescription prescribed by a provider who is not enrolled in the Kentucky Medicaid Program, if the department determines that reimbursing for the emergency supply is in the best interest of the recipient.

Section 11. No Duplication of Service. (1) The department shall not reimburse for a service provided to a recipient by more than one (1) provider of any program in which the service is covered during the same time period.

(2) For example, if a recipient receives a dispensing of a drug prescription from a pharmacist enrolled with the Medicaid Program, the department shall not reimburse for

the same drug prescription dispensing provided to the same recipient during the same time period from another pharmacist.

Section 12. Medicaid Program Participation Compliance. (1) A provider shall comply with:

(a) 907 KAR 1:671;

(b) 907 KAR 1:672; and

(c) All applicable state and federal laws.

(2)(a) If a provider receives any duplicate payment or overpayment from the department, regardless of reason, the provider shall return the payment to the department.

(b) Failure to return a payment to the department in accordance with paragraph (a) of this section may be:

1. Interpreted to be fraud or abuse; and

2. Prosecuted in accordance with applicable federal or state law.

Section 13. Use of Electronic Signatures. (1) The creation, transmission, storage, and other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

(2) A provider that chooses to use electronic signatures shall:

(a) Develop and implement a written security policy that shall:

1. Be adhered to by each of the provider's employees, officers, agents, or contractors;

2. Identify each electronic signature for which an individual has access; and

3. Ensure that each electronic signature is created, transmitted, and stored in a se-

cure fashion;

(b) Develop a consent form that shall:

1. Be completed and executed by each individual using an electronic signature;

2. Attest to the signature's authenticity; and

3. Include a statement indicating that the individual has been notified of his responsibility in allowing the use of the electronic signature; and

(c) Provide the department with:

1. A copy of the provider's electronic signature policy;

2. The signed consent form; and

3. The original filed signature immediately upon request.

Section 14. Auditing Authority. (1) The department shall have the authority to audit any claim or medical record or documentation associated with any claim or medical record.

Section 15. Federal Financial Participation. The department’s coverage of services pursuant to this administrative regulation shall be contingent upon:

(1) Receipt of federal financial participation for the coverage; and

(2) Centers for Medicare and Medicaid Services’ approval for the coverage[~~A provision established in this administrative regulation shall be null and void if the Centers for Medicare and Medicaid Services:~~

~~(1) Denies federal financial participation for the provision; or~~

~~(2) Disapproves the provision~~].

Section 16.[~~12.~~] Appeal Rights. (1) An appeal of an adverse action taken by the department regarding a service and a recipient who is not enrolled with a managed care organization shall be[~~A Medicaid recipient may appeal the department’s denial, suspen-~~

~~sion, reduction, or termination of a covered drug or decision regarding the amount of a drug dispensed based upon an application of this administrative regulation~~] in accordance with 907 KAR 1:563.

(2) An appeal of an adverse action by a managed care organization regarding a service and an enrollee shall be in accordance with 907 KAR 17:010.

Section 17.[~~13.~~] Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Drug Prior Authorization Request Form", May 15, 2007 edition;

(b) "Brand Name Drug Request Form", May 15, 2007 edition;

(c) "Mental Health Drug Authorization Request Form for Atypical Antipsychotic Agents", May 15, 2007 edition;

(d) "Subaxone® and Subutex® Prior Authorization Request Form", September 22, 2009 edition;

(e) "Zyvox® (linezolid) Drug Authorization Request Form", January 11, 2010 edition; and

(f) "Synagis® Prior Authorization Request Form", November 2010 edition.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (Recodified from 904 KAR 1:019, 6-10-86; Am. 15 Ky.R. 2323; eff. 6-21-89; 17 Ky.R. 1871; eff. 12-18-90; 3563; eff. 7-17-91; 23 Ky.R. 3447; 3781; eff. 4-16-97; 25 Ky.R. 1248; 1937; 26 Ky.R. 767; eff. 10-20-99; 27 Ky.R. 1942; 2481; eff. 3-6-2001; 29 Ky.R. 576; 968; eff. 11-13-02; 30 Ky.R. 2405; 31 Ky.R. 358; 712; eff. 8-26-04; 1604; 1990; 32 Ky.R. 267; eff. 8-25-05; 32 Ky.R.

1929; 33 Ky.R. 123; eff. 8-7-06; 37 Ky.R. 557; Am. 1288; Am. 1449; 12-1-2010.)

907 KAR 1:019

REVIEWED:

Date	Lawrence Kissner, Commissioner Department for Medicaid Services

APPROVED:

Date	Audrey Tayse Haynes, Secretary Cabinet for Health and Family Services

907 KAR 1:019

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall, if requested, be held on February 21, 2014 at 9:00 a.m. in Suite B of the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky, 40621. Individuals interested in attending this hearing shall notify this agency in writing by February 14, 2014 five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until February 28, 2014. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, tricia.orme@ky.gov, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: (502) 564-7905, Fax: (502) 564-7573.

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:019
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact: Stuart Owen (502) 564-4321

(1) Provide a brief summary of:
  (a) What this administrative regulation does: This administrative regulation establishes the provisions for coverage of drugs through Medicaid's outpatient pharmacy program.
  (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the provisions for coverage of drugs through Medicaid's outpatient pharmacy program.
  (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing the provisions for coverage of drugs through Medicaid's outpatient pharmacy program.
  (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation currently assists and will continue to assist in the effective administration of the authorizing statutes by establishing the provisions for coverage of drugs through Medicaid's outpatient pharmacy program.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
  (a) How the amendment will change this existing administrative regulation: This amendment eliminates the four (4) prescriptions per recipient per month limit; inserts various program integrity requirements such as that the Department for Medicaid Services (DMS) will not reimburse for the same service provided to a recipient at the same time by two (2) different providers; establishes third party liability requirements (Medicaid is the payor of last resort); establishes general provider participation requirements (program integrity requirements); establishes the option of using electronic signatures along with corresponding requirements; and establishes that DMS's coverage of drugs under this administrative regulation is contingent upon federal approval and federal funding.
  (b) The necessity of the amendment to this administrative regulation: This amendment is necessary to synchronize the Department for Medicaid Services' coverage of outpatient drugs with the alternative benefit plan established by DMS to be effective January 1, 2014. An alternative benefit plan is mandated by the Affordable Care Act for any state which adds the Medicaid "expansion group" to its eligibility groups. The alternative benefit plan is the array of benefits available to the expansion group and must be based on a "benchmark" or "benchmark equivalent plan." There are four (4) acceptable

such plans as established by 42 C.F.R. 440.330 and 42 U.S.C. 1396u-7(b). The four (4) are:

- The benefit plan provided by the Federal Employees Health Benefit plan Standard Blue Cross/Blue Shield Provider Option;
- The state employer health coverage that is offered and generally available to state employees;
- The health insurance plan offered through the Health Maintenance Organization (HMO) with the largest insured commercial non-Medicaid enrollment in the state; and
- Secretary-approved coverage, which is a benefit plan that the secretary has determined to provider coverage appropriate to meet the needs of the population provided that coverage.

States are required to cover every service in the given alternative benefit plan and may not pick and choose services from different alternative benefit plan options.

Kentucky selected a benchmark plan that is in the category of Health and Human Services Secretary-approved coverage. The specific plan is the Anthem Blue Cross Blue Shield Small Group Provider Preferred Option (PPO). As this plan imposed no prescription drug limit, DMS is removing the four (4) prescription per recipient per month limit. Also, DMS is adopting the same benefit plan for all Medicaid recipients (those eligible under the “old” rules as well as under the “new” rules.)

The no duplication of service amendment, the amendment requiring providers to comply with Medicaid program participation requirements established in 907 KAR 1:671 and 907 KAR 1:672, and the third party liability requirement is necessary to maintain program integrity and prevent the misuse of taxpayer revenues. The electronic signature requirements are necessary to allow providers to use electronic signature and ensure that they comply with the requirements established for such in Kentucky law. Establishing DMS’s coverage of prescription drugs is contingent upon federal approval and federal funding is necessary to protect Kentucky taxpayer revenues from being spent if no federal funding is provided.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by comporting with the Affordable Care Act, enhancing program integrity of Medicaid benefits, and protecting taxpayer revenues.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in the effective administration of the authorizing statutes by comporting with the Affordable Care Act, enhancing program integrity of Medicaid benefits, and protecting taxpayer revenues.

(3) List the type and number of individuals, businesses, organizations, or state and

local government affected by this administrative regulation: All Medicaid-reimbursed prescribing providers are affected by this amendment and recipients are affected as well.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Providers will need to continue to ensure that they bill appropriately.
(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No cost is imposed.
(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Medicaid recipients will benefit by no longer being limited to four (4) prescriptions per month; however, the limit was not a hard limit.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:
(a) Initially: DMS anticipates little if any increased costs as a result of lifting the four (4) prescription per month limit as the limit was “soft” (could be over-ridden if medically necessary.)
(b) On a continuing basis: DMS estimates DMS anticipates little if any increased costs as a result of lifting the four (4) prescription per month limit as the limit was “soft” (could be over-ridden if medically necessary.)

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX of the Social Security Act and state matching funds of general fund appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding is necessary to implement this amendment.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? (Explain why tiering was or was not used)
Tiering was not appropriate in this administrative regulation as the administrative regulation applies equally to all those individuals or entities regulated by it.

FEDERAL MANDATE ANALYSIS COMPARISON

Regulation Number: 907 KAR 1:019
Agency Contact: Stuart Owen (502) 564-4321

1. Federal statute or regulation constituting the federal mandate. 42 C.F.R. 440.330 and 42 U.S.C. 1396u-7(b).

2. State compliance standards. KRS 205.560 establishes "The scope of medical care for which the Cabinet for Health and Family Services undertakes to pay shall be designated and limited by regulations promulgated by the cabinet, pursuant to the provisions in this section."

3. Minimum or uniform standards contained in the federal mandate. This amendment is necessary to synchronize the Department for Medicaid Services' coverage of outpatient drugs with the alternative benefit plan established by DMS to be effective January 1, 2014. An alternative benefit plan is mandated by the Affordable Care Act for any state which adds the Medicaid "expansion group" to its eligibility groups. The alternative benefit plan is the array of benefits available to the expansion group and must be based on a "benchmark" or "benchmark equivalent plan." There are four (4) acceptable such plans as established by 42 C.F.R. 440.330 and 42 U.S.C. 1396u-7(b). The four (4) are:
   - The benefit plan provided by the Federal Employees Health Benefit plan Standard Blue Cross/Blue Shield Provider Option;
   - The state employer health coverage that is offered and generally available to state employees;
   - The health insurance plan offered through the Health Maintenance Organization (HMO) with the largest insured commercial non-Medicaid enrollment in the state; and
   - Secretary-approved coverage, which is a benefit plan that the secretary has determined to provider coverage appropriate to meet the needs of the population provided that coverage.

   States are required to cover every service in the given alternative benefit plan and may not pick and choose services from different alternative benefit plan options.

Kentucky selected a benchmark plan that is in the category of Health and Human Services Secretary-approved coverage. The specific plan is the Anthem Blue Cross Blue Shield Small Group Provider Preferred Option (PPO). As this plan imposed no prescription drug limit, DMS is removing the four (4) prescription per recipient per month limit. Also, DMS is adopting the same benefit plan for all Medicaid recipients (those eligible under the "old" rules as well as under the "new" rules.)

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal

mandate? No.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. It does not impose stricter standards or requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 907 KAR 1:019
Agency Contact: Stuart Owen (502) 564-4321

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services is affected by the amendment.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. This amendment is authorized by this administrative regulation.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

   (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate any additional revenue for state or local governments during the first year of implementation.
   (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate any additional revenue for state or local governments during subsequent years of implementation.
(c) How much will it cost to administer this program for the first year? No additional costs are necessary to implement this amendment during the first DMS anticipates little if any increased costs as a result of lifting the four (4) prescription per month limit as the limit was “soft” (could be over-ridden if medically necessary.)
   (d) How much will it cost to administer this program for subsequent years? No additional costs are necessary to implement this amendment during subsequent years. DMS anticipates little if any increased costs as a result of lifting the four (4) prescription per month limit as the limit was “soft” (could be over-ridden if medically necessary.)

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.
Revenues (+/-): ____
Expenditures (+/-): ____
Other Explanation: